



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, 28 June 2005
Doc. Ref. EMEA/160725/2005

The Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
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Rockville
MD 20852-1448
USA

Dear Sirs,

Letter in response to Docket 2004N-0539

In the EU, European Pharmacopoeia monographs are mandatory standards for medicines. The monograph 0853 on Human Plasma for Fractionation defines freezing, storage and transport conditions for plasma intended for fractionation. The European Pharmacopoeia will be providing information on the Pharmacopoeia requirements and their scientific rationale in response to this Docket, and has also provided input to the 2004 Workshop and comments to the previous Docket No. 2003N-0211.

The European Medicines Agency is responsible for the Certification of Plasma Master Files for plasma used in the manufacture of plasma-derived medicinal products authorised in the EU. During the evaluation of applications for Certification, and associated inspections of collection, storage and transport sites, issues have arisen with some US sites because of non-compliance with European Pharmacopoeia requirements for freezing and storage of plasma units intended for fractionation.

There is a strong need for harmonised, scientifically based requirements between Europe and USA with respect to standards for freezing and storage of plasma intended for manufacture of plasma-derived medicinal products. It would be highly desirable if this could be achieved as an outcome of this FDA initiative.

Yours sincerely,

SIGNED

Dr John Purves
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